REMARKS

Claims 16-30 and 32-34 presently appear in this case. Claims 6-14 and 16-33 have been withdrawn from consideration. No claims have been allowed. The official action of April 9, 2004, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a method of treating host vs. graft disease (HVGD), i.e., graft or transplant rejection, by administering Copolymer 1 or a Copolymer 1-related random copolymer to a mammal that is a transplant recipient. The invention is also directed to a method for treating or preventing graft vs. host disease (GVHD) by administering a Copolymer 1-related copolymer that is not Copolymer 1.

The examiner has considered applicants' traversal of the previous restriction requirement but has refused to withdraw it, stating that, in this case, the existing rules do not confer "immunity" from restriction. The examiner refers to an amendment to PCT Rule 13.2 that was modified effective July 1, 1992, and states that a special technical feature still must exist between the compound and its method of use. This restriction requirement is again respectfully traversed.

Regardless of the present wording of PCT Rule 13.2, it must be considered in light of the applicable U.S. regulations. Here, the applicable regulation is 37 C.F.R. §1.499, which relates to unity of invention during the national stage. This rule states that election may be

required if "the examiner finds that a national stage application lacks unity of invention under §1.475." 37 C.F.R. §1.475(a) states:

> (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). ...

37 C.F.R. §1.475(b) goes on to state in pertinent part:

> (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
>
> ...
>
> (2) a product and a process of use of said product; ....

It must be noted that this regulation clearly states that a product and a process of use of said product "will be considered to have unity of invention". Thus, this is completely independent of the discussion of special technical features. The terminology "specially adapted for" does not appear in 37 C.F.R. §1.475(b)(2) as it appears in other sub-paragraphs of this regulation. Thus, the restriction requirement should not have been made, and it must be withdrawn.

Reference is made to MPEP §1850 A. "Combinations of different categories of claims", where it states:

> A method for determining unity of invention under PCT Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of

> claims of different categories in the same international application:
>
> (A) In addition to an independent claim for a given product, ... an independent claim for a use of the said product ....

In the same MPEP section, the first full paragraph on page 1800-98 (Rev. 2, May 2004), states:

> In particular, while a single set of independent claims according to one of (A), (B), or (C) above is always permissible, it does not require the international authority to accept a plurality of such sets which could arise by combining the provisions .... [Emphasis added]

Thus, the MPEP makes it clear that an independent claim for a given product and an independent claim for use of said product is always permissible. Accordingly, the examiner's discussion of special technical features and the unpatentability of the product claims is irrelevant. 37 C.F.R. §1.499 and §1.475(b) do not permit the examiner to require an election between a product and a process of use thereof. Accordingly, reconsideration and withdrawal of the restriction requirement is respectfully urged.

Claims 1-5 and 15 have been rejected under 35 U.S.C. §101, 35 U.S.C. §112, 35 U.S.C. §102 and 35 U.S.C. §103 on varying grounds and over various reference. These rejections are respectfully traversed.

Claims 1-15 have now been deleted, thus obviating all of these rejections. As the requirement for restriction must be withdrawn for the reasons discussed above, claim 16-33 and new claim 34, which are drawn to methods of use of the deleted compositions, must now be considered. As none of the

references cited by the examiner teach or make obvious the use of Copolymer 1 for the treat of HVGD (graft or transplant rejection) or the use of copolymers other than Copolymer 1 as defined in the claims for the treatment of GVHD or HVGD, all of the claims now present in the case should be in condition for allowance. Reconsideration and withdrawal of all of these rejections are therefore respectfully urged.

All of the claims now present in the case fully comply with 35 U.S.C. §112 and clearly define over the references of record. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

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